federal public service
HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT

Risk Management Option Analysis Conclusion Document

Substance Name: 2,4,6-tri-tert-butylphenol (2,4,6-TTBP)

EC Number: 211-989-5

CAS Number: 732-26-3

Authority: BE CA

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	X
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Harmonised classification and labelling

2,4,6-TTBP is covered by Index number 604-097-00-6 in part 3 of Annex VI to the CLP Regulation as follows (it shall apply as from 23 November 2023):

Table 3: Harmonised Classification in Annex VI of the CLP

Index No	**Chemical name**	**EC No**	**CAS No**	**Classification**		**Labelling**			**Spec. Conc. Limits, M-factors and ATEs[2]**	**Notes**
				Hazard Class and Category Code(s)	**Hazard statement code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement code(s)**	**Suppl. Hazard statement code(s)**		
604-097-00-6	2,4,6-tri-tert-butyl phenol	211-989-5	732-26-3	Repr. 1B Acute Tox. 4 STOT RE2 Skin Sens. 1B	H360D H302 H373 (liver) H317	GHS08 GHS07 Dgr	H360D H302 H373 (liver) H317		Oral: ATE = 500 mg/kg bw	

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

[2] Acute Toxicity Estimate

2,4,6-TTBP is covered by index number 604-097-00-6 in part 3 of Annex VI to the CLP Regulation.

Therefore, the substance can be identified as SVHC:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

Furthermore, a weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to identify the Substance as PBT/vPvB. All available information (such as the results of standard tests, non-standard tests and (Q)SAR results) was considered together in a weight-of-evidence approach.

Persistence

2,4,6-TTBP is not readily biodegradable according to QSAR estimations (EPIWEB v4.1; BIOWIN v4.10)

2,4,6-TTBP is not inherently biodegradable based on the results of an OECD TG 302C study.

Further data indicate that 2,4,6-TTBP is persistent and very persistent, based on a weight-of-evidence approach (half-life in seawater is 92 days at relevant EU temperature).

Bioaccumulation

2,4,6-TTBP has the potential to bioaccumulate according to QSAR estimations (EPIWEB v4.1; BCFBAF v3.01).

The B/vB criterion (Annex XIII of REACH) is fulfilled for 2,4,6-TTBP based on a Japanese Guideline Study (BCF values range from 4 320 to 23 200 L/kg at 0.001 ppm w/v and 4 830 to 16 000 L/kg at 0.01 ppm w/v).

Toxicity

2,4,6-tri-tert-butylphenol is covered by index number 604-097-00-6 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances). It is classified in the hazard class toxic for reproduction category 1B (H360D: May damage the unborn child) and STOT RE category 2 (H373: May cause damage to organs (liver) through prolonged or repeated exposure).

Therefore, the substance can be identified as SVHC:

- PBT/vPvB in accordance with articles 57(d) and (e) of REACH.

An identification as SVHC according to article 57 (c), (d) and (e) would create legal certainty and oblige the registrant(s) to review their risk management measures and provide advice on safe use to downstream users. The authorization process furthermore provides an incentive for substitution to safer alternatives.

Based on the conclusion above, 2,4,6-TTBP is proposed to be identified as a substance of very high concern in accordance with Article 57 (c), (d) and (e) of Regulation (EC) 1907/2006 (REACH).

3.3 Restriction under REACH

Restriction can be introduced when there is an unacceptable risk to human health and/or the environment, arising from the manufacture, placing on the market (including imports) or the use of the substances, which needs to be addressed on a Community-wide basis. A

restriction may apply to any substance on its own, in a mixture or in an article. Restriction procedure also takes into account the socio-economic impact of the restriction, including the availability of alternatives. If it can be demonstrated that there is a Community-wide risk, which is not adequately controlled for certain uses of substances, a restriction process according to REACH Articles 69(1) and 69(4) should be started.

Exposure and emissions to the environment can be expected from the uses of the Substance. However, little measured data on discharges or monitoring data on actual environmental concentrations are currently available. Consequently, it is now not possible to demonstrate whether there is a Community-wide risk and to quantify the risk in an accurate manner. Information on potential alternatives is not available either. Therefore, restriction is considered not the best risk management option at the moment for this substance.

3.4 Other Union-wide regulatory measures

Not applicable.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Not applicable.

5. NO ACTION NEEDED AT THIS TIME

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actor
Annex XV dossier for SVHC identification	August 2023	BE CA